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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/693,833

10/24/2003

Marcel Limousin

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1007

7590 02/25/2009
Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103

EXAMINER

ALTER, ALYSSA MARGO

ART UNIT	PAPER NUMBER
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3762

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02/25/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/693,833	Applicant(s) LIMOUSIN ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, filed August 14, 2008 with respect to the rejection(s) of claim(s) 1-13, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Bourgeois et al. and Scheiner et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3, 5-10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Bourgeois et al. (US 6,126,611). Bourgeois et al. discloses sensing respiratory activity to determine sleep apnea, for example col. 3, lines 26-29 and measuring hemodynamic state. Bourgeois et al. determines heart rate, which the examiner considers contractility of the myocardium. Once apnea is detected, Bourgeois et al. employs over-drive pacing, or higher than normal pacing stimulation, to terminate

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the apnea. This treatment, depicted in figure 1, paces the heart at a high rate and causes the patient to awaken..

“Where apnea is detected through minute ventilation, if the apnea persists for a predetermined time, e.g. 10 seconds, the cardiac pacing rate switches to the higher rate. This mode switch can be abrupt or gradual. After a fixed period of time, or when the apnea is terminated, pacing is then withdrawn” (col. 5, lines 56-61).

As to claim 10, “pacemaker 10 is capable of operating in various non-rate-responsive modes which include DDD, DDI, VVI, VOO, AOO, VDD. DVI, AAT and VVT, as well as corresponding rate-responsive modes of DDDR, DDIR, VVIR, VOOR and VVTR. Further, pacemaker 10 can be programmably configured to operate such that it varies its rate only in response to one selected sensor output, or in response to both sensor outputs, if desired”(col. 5, lines 14-22). Therefore, since Bourgeois et al. discloses the employment of a multi-site pacemaker, Bourgeois et al delivers multi-site stimulation.

2. Claims 1-3, 5-10 and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Scheiner et al. (US 6,415,183 B1). Scheiner et al. depicts in figure 5, a system to treat "respiratory ailments such as sleep apnea" (col. 1, line 66). Additionally, “the respective diaphragm and hear therapies are deliver either concurrently or independently in blocks 706A and 706B” (col. 10, lines 37-39)

“Device 170 is a pulse generator such as a bradycardia or antitachycardia pacemaker, a cardioverter, a defibrillator, a combination pacemaker/defibrillator, or other device for providing therapy to a heart or diaphragm” (col. 4, lines 39-42).

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“Signal processing circuit 226 is a circuit for receiving, processing and filtering electrical signals sensed by electrodes implanted in a body. Signal processing circuit 226 contains amplifiers and circuits to filter and amplify the electrical signals delivered via a lead. Examples of such signals include signals such as transthoracic impedance or heart activity signals. These signals are representative of a patient's physiological state. For example, if a lead such as lead 130 is inserted into or placed near a heart, signal processing circuit 226 can detect an impedance level between electrode 131 and can electrode 172 and an impedance level between ring electrode 132 and can electrode 172” (col. 5, lines 31-42).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claim 4 is rejected under 35 U.S.C. 103(a) as obvious over Scheiner et al. (US 6,415,183 B1). Scheiner et al. discloses the monitoring of impedance, but is silent as to intracardiac impedance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ measurements of intracardiac impedance to determine hemodynamic performance since it is well known in the art to sense intracardiac impedance in determining cardiac health and well-being.

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Furthermore, measuring intracardiac impedance would provide the predictable results of monitoring the hemodynamic performance and provide indication of the cardiac health.

2. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 6,126,611). Bourgeois et al. discloses the device substantially as claimed but fails to teach measuring intracardiac impedance. It would have been obvious to one having ordinary skill in the art at the time the invention was made to employ measurements of intracardiac impedance to determine hemodynamic performance since it is well known in the art to sense intracardiac impedance in determining cardiac health and well-being. Furthermore, measuring intracardiac impedance would provide the predictable results of monitoring the hemodynamic performance and provide indication of the cardiac health.

3. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourgeois et al. (US 6,126,611) or Scheiner et al. (US 6,415,183 B1). Bourgeois et al. and Scheiner et al. teach the device substantially as claimed but fail to teach comparing a hemodynamic signal to an average of the hemodynamic signals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system to include comparing hemodynamic signals to an average in order to provide the predictable results of observing a change in the system from previously measured standards and providing a threshold to the modification or initiation of treatment.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
Art Unit 3762